



DOCKET NO. P-7109.03 C1

3763
PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AMENDMENT TRANSMITTAL

Applicants: Jesus Casas-Bejar et al.

Examiner: Thissell, Jeremy

Serial No.: 09/998,536

Group Art Unit: 3763

Filed: November 28, 2001

Docket: P-7109.03 C1

Title: Medical Electrical Leads and Indwelling Catheters with Enhanced Biocompatibility and Biostability

CERTIFICATE OF MAILING UNDER 37 CFR 1.8: I hereby certify that this **Amendment Transmittal** and the paper(s), as described herein, are being deposited in the U.S. Postal Service, as first class mail, addressed to the Mailstop Amendment, P.O. Box 1450, Commissioner for Patents, Alexandria, VA 22313-1450 on this 29 day of December, 2004.

Juanita I. Traufler
Juanita I. Traufler

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

- ☒ Amendment Transmittal
- ☒ Resubmitted Reply Under 37 CFR 111 & Amendment Under 37 CFR 1.121
- ☒ Amended Claims
- ☒ Return Postcard

FEE CALCULATION

CLAIM AMENDMENT(S)	Claims Remaining After Amendment	Highest Number Previously Paid For	Add'l Claims	Rate	Fee
Total Claims	8 -	18 =		x 50	\$00.00
Independent Claims	2 -	5 =		x 200	\$00.00
Multiple Dependent Claims	No			+ 360	\$
TOTAL					\$00.00

Applicant hereby petitions for a ____ month extension of time in the prior application. If an additional extension of time is required, please consider this a petition therefor;

Charge Deposit Account No. 13-2546 the sum of \$
\$240.00 pursuant to 37 CFR §1.97(c) without 37 CFR §1.97(e) certification

XX Please charge any additional fees or credits to Deposit Account No. 13-2546 which may have been overlooked on this Amendment Transmittal with regard to this filing. A duplicate of this transmittal is enclosed.

XX Applicant believes that no extension of term is required. However, if an extension of time is required, please consider this a petition therefor to provide for the possibility that applicant has inadvertently overlooked the need for an extension of time.

December 29, 2004
Date

Kenneth J. Collier
Kenneth J. Collier, Reg. No. 34,982
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date appearing below.

Medtronic Inc.

By Juanita I. Traufler
Juanita I. Traufler

Date December 29, 2004

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Jesus W. Casas-Bejar, Darrel F. Untereker, Maura G. Donovan, Qinghong Zhao, Brian C.A. Fernandes, Timothy H. Robinson, Peter T. Schroeder

Serial No. : 09/998,536

Group Art Unit 3763

Filed : 11/28/2001

Examiner: Thissell, Jeremy

For : Medical Electrical Leads and Indwelling Catheters with Enhanced Biocompatibility and Biostability

Docket No. : P7109.03 C1

RESUBMITTED REPLY UNDER 37 C.F.R. 111 &
AMENDMENT UNDER 37 C.F.R. 1.121

Mail Stop Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants re-submit their response in support of US Application Number 09/998,536. Applicants received the Examiners reply dated 12/01/2004 providing an additional 1-month time to submit revised amendments. The Examiner found the submitted amendments as non-responsive because they were found to place the claims outside the scope of the previously elected invention.

Applicants re-submit cancelled claims, amended claims, and arguments to forward prosecution. Applicant's response is submitted in reply to the office action

dated March 9, 2004. In the previous Office Action received by the Applicants, the Examiner rejected pending claims 1-6, 11, 12, 26, 30, and 31.

Applicants submitted with their original response a request for a three month extension of time and authorize the office to charge deposit account No. 13-2546, in the name of Medtronic, Inc., the fee under 37 C.F.R. §1.17(c) for any additional fees necessary related to this application. Applicants were given an additional 1 month of time to resubmit their response (extendable under 37 CFR 1.136).

Applicants also wish to thank Examiner Desantas for his time on August 26, 2004 to discuss the case, and to provide helpful suggestions towards moving the instant case towards allowance, and for permitting the Applicants to resubmit their response.

Claim Amendments

- Please cancel, without prejudice, claims 12, 28, 31-32, and 35.
- Please amend claims 1 and 26 as indicated in the attached amendment sheet.

Claims 1 and 26, have been restructured to additionally provide a medical electrical lead comprising: 1) the insulative lead body of the electrical leads which are not formed with a steroidal anti-inflammatory agent, and 2) a polymer overcoating of said lead body providing a tissue-contacting surface and having an active agent intimately mixed with the polymer, and wherein said overcoating is chosen such that said polymer and said active agent are free of micron sized particulates.

Claim 30 has been amended to claim the process of overcoating the medical electrical lead to additionally provide that the overcoating is chosen such that said polymer and said active agent are free of micron sized particulates and that the insulative lead body is not formed with a steroidal anti-inflammatory agent.

Claims 12, 28, and 31 and 32 have been cancelled.

Support for amendments for adding the overcoating free of micron sized particles is found in the specification and the prior art (see Fearnot and Helmus discussed herein):

In one embodiment, the polymer of the tissue-contacting surface and an anti-inflammatory agent are intimately mixed either by blending or using a solvent in which they are both soluble (e.g., xylene for silicone and dexamethasone phosphate). This mixture can then be formed into the desired shape and incorporated into the medical device or coated onto an underlying structure of the medical device [Applicants Specification – Page 13, last paragraph]

Alternatively, an overcoating polymer, which may or may not be the same polymer that forms the primary polymer of the tissue-contacting surface, and an anti-inflammatory agent are intimately mixed, either by blending or using a solvent in which they are both soluble, and coated onto the tissue-contacting surface. [Applicants Specification – Page 14, first paragraph]

Applicants specification clearly teaches that an overcoating polymer is either blended or using a solvent which both the polymer and active agent a soluble. This inherently provides that their would not be particulates as described by Helmus, however, applicants have expressly put the physical limitation of not having micron sized particulates in the claims to clarify their polymers from those of Helmus (polymer structures of Helmus being known in the art).